## **AUSTRALIA**

# Patents Act 1990

IN THE MATTER OF
US Patent Application No. 09/446,109
by The University of Queensland

#### **EXHIBIT VBS-1**

This is Exhibit VBS-1 referred to in the Statutory Declaration by Vivien Bedford Santer dated 13 may 2004

Before me:

SALLY ANN SHRIMPTON
3rd Floor, 509 St. Kilda Rd, Melbourne 3004
A current practitioner within the meaning
of the Legal Practice Act 1996.

A person empowered to witness Statutory Declarations under the laws of the Victoria, Commonwealth of Australia

## CURRICULUM VITAE - DR VIVIEN SANTER

Date of Birth:

February 6th, 1949

## University Education:

B.Sc. University of Melbourne, 1967-1969.

First year:

Pure Mathematics I Chemistry IA Physics IA

Honours IIA Honours III Biology Honours I

N.B. - Chemistry IA and Physics IA were Honours level

subjects.

Second year:

Chemistry IIB

Honours I

Honours IIB

(second in class)

Physiology and Biochemistry Honours III (This subject included a Histology unit) General Microbiology Honours I

Third Year:

Biochemistry II

Honours IIA Honours I Honours IIA

Virology Bacteriology

Australian Society for Microbiology Prize for Virology

#### B.Sc. (Hons) University of Melbourne 1970

A research project was carried out in the Electron Microscopy Laboratory at the Walter and Eliza Hall Institute of Medical Research under the supervision of Dr T.E. Mandel. The Honours thesis was entitled "Light and electron microscope studies on antigen-binding in vitro in the immune response".

Received Honours IIA.

#### Ph.D. - University of Melbourne 1974.

Research work was carried out in the same laboratory under the supervision of Professor G.J.V. Nossal (now Sir Gustav Nossal) and Dr T.E. Mandel. The thesis was entitled "Ultra-structural and functional studies on lymphocyte membranes: surface immunoglobulin receptors and the surface coat".

#### Positions Held:

(1) Senior Tutor, Department of Biochemistry, Monash University, Melbourne, Australia.

January 1974 - November 1976

#### Subject of Research

- Light and electron microscope studies on carrageenin-induced arthritis and antigen-induced arthritis in the rabbit. These systems are used as models for human rheumatoid arthritis.
- 2. Radioautographic studies on cartilage metabolism in model systems for arthritis.

The position entailed extensive tutoring and laboratory class demonstrating to second year Science students, plus some lecturing.

(2) Research Associate, Department of Anatomy, McGill University, Montreal, Canada.

January 1977 - In Dr P.K. Lala's laboratory

#### Subject of Research

- 1. Spontaneous fusion between Ehrlich ascites tumour cells and host cells in vivo, using surface H-2 antigens as a marker detected by sandwich radioimmunolabelling and radioautography.
- 2. Studies on lymphocyte populations in mice bearing transplanted or spontaneous tumours, with reference to their subsets as determined by labelling with anti-Ig, anti-Thy 1.2, and anti-Ly antibodies.
- 3. Studies on the function of lymphocytes from mice with transplanted and spontaneous tumours in natural cytotoxicity assays *in vitro* and *in vivo*.

Dr Santer was in charge of the laboratory from June 1977 to July 1978 during Dr Lala's absence on sabbatical leave; this involved supervision of two M.Sc. students and two technicians

From September 1978 to October 1979 she was jointly responsible for supervision of a B.Sc. (Hons.) student.

(3) Post-doctoral Fellow, Joint Diseases Laboratory, Shriners' Hospital for Crippled Children, Montreal, Canada. In collaboration with Dr P.J. Roughley, carrying out studies on the proteoglycans of connective tissues.

#### Subject of Research

- 1. Studies on changes in the physical and chemical properties of proteoglycans from normal and degenerate cartilage of the human tibial plateau.
- 2. Studies on the physical and chemical properties of proteoglycans from normal human articular cartilage and their changes with age.
- Studies on the oligosaccharide moiety of human articular cartilage proteoglycan.
- Studies on a latent proteoglycan-degrading enzyme in medium from human fibroblasts and synovial cells cultured in the presence of mononuclear cell factor (in collaboration with Dr Elaine Golds).
- (4) Research Fellow, Departments of Physiology and Biochemistry, Monash University, 1982 (Part-time).
  - In collaboration with Dr C.J. Handley, Ms A. Fosang and Professors D.A. Lowther and G.D. Thorburn, carrying out morphological studies on changes occurring in the uterine cervix of the sheep during gestation and parturition.
- (5) Research Fellow, Dean's Department, Faculty of Medicine, Monash University 1983 (Part-time).
  - In collaboration with the Dean of Medicine, Professor G.C. Schofield, performing electron microscopic studies on acid secretion in the stomach, and on the effect of Epidermal Growth Factor on gastric parietal and chief cells.
- (6) Joined Griffith Hack (then called Clement Hack & Co.), Patent and Trade Mark Attorneys, Melbourne in June 1984 as a Technical Assistant.

Completed the examinations for registration as a Patent Attorney in 1986, with Distinctions in Patents and Designs, and Credit in Trade Marks.

Registered as a Patent Attorney, December 1986.

Fellow of the Institute of Patent Attorneys of Australia, February 1987.

Became a partner of the firm in July 1990.

Responsible for preparation, filing and prosecution of Australian and foreign patent applications in all fields relating to biotechnology, particularly biochemistry,

microbiology, and immunology, as well as general pharmacology and pharmaceutical chemistry; patent oppositions, searches, general advice, opinions and litigation support in these fields.

### Teaching Experience:

- Part-time demonstrator in General Microbiology 1970-1971 (University of Melbourne).
- Tutor and demonstrator in Biochemistry 203 1974-1976 (Monash University).
- Lecturer in Biochemistry 205 1975-1976 (Monash University).
- Supervision of B.Sc (Hons.) students 1974-1975 (Monash University); 1978 (McGill University).
- Supervision of M.Sc. students 1977-1978 (McGill University).

#### Other Activities

Dr Santer was invited to be the first Chairman of the Patents and Licensing Working Party of the Australian Biotechnology Association, and held that position from the inception of the Working Party in 1987 until 1997. The Working Party liases between the academic and industrial research communities and the patent and legal professions, and has made submissions to the Biotechnology Consultative Group of the Australian Department of Industry, Technology and Commerce and to the Minister on various matters. In1997 the Working Party was replaced by the Intellectual Property Group, of which Dr Santer is a member. Dr Santer contributes a regular column to the bi-monthly Journal of the Association, and is a member of the organising committee of the Association's Victorian branch. Dr Santer was also a member of the Victorian Organising Committee of the Intellectual and Industrial Property Society from 1987 to 1989.

Dr Santer has given lectures in management of intellectual property in the CSIRO training course for Divisional business managers and senior scientific staff, and frequently gives presentations on patenting at scientific and other conference, as well as contributing papers on patenting and intellectual property to journals in the biotechnology field.

In 1995, Dr Santer accepted a Ministerial appointment to the Board of Patent Attorneys Professional Standards, and was the primary examiner for the Patents subject for registration as a patent attorney from 1995 to 1997.

Since 1996 Dr Santer has been a non-executive director of Rothschild's Australasian Bioscience Investment Trust, now independent of Rothschild and called GBS Venture Partners Ltd.

In March 2003 Dr Santer accepted an invitation to join the Advisory Committee on genetics, intellectual property rights and human health care, assisting the Australian Law Reform Commission with a reference from the Federal Government on "Intellectual Property Rights Over Genetic Material and Genetic and Related Technologies"

#### Membership of Professional Societies:

- Australian Society for Biochemistry and Molecular Biology

- Australian Biotechnology Association
  Intellectual Property Society of Australia and New Zealand
  Licensing Executives' Society
  International Federation of Industrial Property Attorneys
  Asian Patent Attorneys' Association

#### **PUBLICATIONS**

- Marchalonis, J.J., R.E. Cone and V. Santer.
   "Enzymic Iodination. A Probe for Accessible Surface Proteins of Normal and Neoplastic Lymphocytes"
   Biochem. J. 1971 124 921.
- Santer, V., A.D. Bankhurst and G.J.V. Nossal.
   "Ultrastructural Distribution of Surface Immunoglobulin Determinants on Mouse Lymphoid Cells"
   Exptl. Cell Research 1972 72 377.
- Santer, V., R.E. Cone and J.J. Marchalonis.
   "The Glycoprotein Surface Coat on Different Classes of Murine Lymphocytes" Exptl. Cell Research 1973 79 404.
- Santer, V.
   "Ultrastructural Radioautographic Studies on Capping and Endocytosis by Mouse Spleen Lymphocytes"
   Aust. J. Exp. Biol. Med. Sci. 1974 <u>52</u> 241.
- Santer, V.
   "The Surface Coat on Mouse Lymphocytes"
   Proc. 8th International Congress on Electron Microscopy, Canberra, 1974 Vol. II p. 242.
- Mandel, T.E. and V. Santer.
   "Ultrastructural of the Lymphocyte Surface" In The Lymphocyte- Structure and Function"
   Ed. J.J. Marchalonis (Marcel Dekker Inc., N.Y.) 1977 pp. 511-529.
- Santer, V.
   "The Cell Coat or Glycocalyx of Lymphocytes".
   Ibid. pp. 541-564.
- Carmichael, D.J., G.C. Gillard, D.A. Lowther, C.J. Handley and V. Santer.
   "Carrageenin-Induced arthritis. IV. Rate Changes in Cartilage Matrix Proteoglycan Synthesis"
   Arth. Rheum. 1977 20 834.
- Lowther, D.A., J.D. Sandy, V. Santer and H.L.G. Brown.
   "Antigen-Induced Arthritis: Decreased Proteoglycan Content and Inhibition of Proteoglycan Synthesis in Articular Cartilage" Arthr. Rheum. 1978 <u>21</u> 675.
- Lala, P.K., S. Garnis, L. Kaizer, S. Jacobs and V. Santer
   Characterization of Lymphocytes Invading Experimental Tumours. Proceedings of the International Conference on Germinal Centers in Immune Responses, Damp, West Germany, 1978.

   Adv. Exp. Med. Biol. 1979 <u>114</u> 778-781.

- Santer, V., J.H. Mastromarino and P.K. Lala.
   "Characterization of Lymphocyte Subsets in Spontaneous Mouse Mammary Tumours and Host Lymphoid Organs"
   Int. J. Cancer 1980 <u>25</u> 159-168.
- 12. Lala, P.K., V. Santer and K.S. Rahil "Spontaneous Fusion Between Ehrlich Ascites Tumour Cells and Host Cells In Vivo: Kinetics of Hybridisation and Concurrent Changes in the Histocompatibility Profile of the Tumour after Propagation in Different Host Strains" Eur. J. Cancer 1980 16 387-510.
- Chatterjee-Hasrouni, S., V. Santer and P.K. Lala.
   "Changes in the Maternal Lymphoid System During Syngeneic and Allogeneic Pregnancy in the Mouse"
   Cell. Immunol. 1980 <u>50</u> 290-304.
- Santer, V., J.H. Mastromarino and P.K. Lala.
   "Characterization of Small Lymphocyte Subsets in Mice Bearing Spontaneous Mammary Tumours"
   Fed. Proc. 1979 38 992.
- Lala, P.K., V. Santer and J. Mastromarino.
   "Characterization of Small Lymphocyte Subsets in Mice Bearing Spontaneous Mammary Tumours"
   Annual Meeting of the Canadian Federation of Biological Societies, 1979.
- Osmond, D.G., V. Santer and N. Saveriano.
   "Radioautographic Studies of Lectin Binding by Small Lymphocytes in Mouse Bone Marrow, Thyrnus and Spleen"
   Annual Meeting of the Canadian Federation of Biological Societies, 1979.
- 17. Saveriano, N., N. Drinnan, V. Santer and D.G. Osmond.

  "Lectin-Binding Patterns of Small Lymphocytes in Bone Marrow, Thymus and Spleen: Demonstration of Lymphocyte Subsets by Quantitative Radioautogrpahy" Eur. J. Immunol. 1981 11 870-876.
- Santer, V., P.J. Roughley and R. White
   "Proteoglycans from Normal and Degenerate Cartilage of the Human Tibial Plateau"
   Arthr. Rheum. 1981 24 691-700.
- Roughley, P.J., R. White and V. Santer
   "Comparison of Proteoglycans Extracted from High and Low Weight-Bearing Human Articular Cartilage, with Particular Reference to Sialic Acid Content"
   J. Biol. Chem. 1981 <u>256</u> 12690-12704
- Roughley, R.J., D. McNicol, V. Santer and J. Buckwalter.
   "The Presence of a Cartilage-Like Proteoglycan in the Adult Human Meniscus" Biochem. J. 1981 197 77-83.

- Santer, V., E. Golds, R.J. White and P.J. Roughley.
   "Mononuclear Cell Factor (MCF) Stimulates Release of a Proteoglycan- Degrading Enzyme form Human Skin Fibroblasts and Synovial Cells"
   Arthr. Rheum. 1981 24 S118.
- Osmond, D.G., N. Saveriano, M. Drinnan, V. Santer, M.D. Rahal, J.J.T. Owen and A.M. Rijnbeek.
   "Lectin Binding by Bone Marrow Lymphocytes: Pre-B Cells have a Surface Receptor for Peanut Agglutinin"
   Developments in Immunology 1981 15 103-110.
- Santer, V., R.J. White and P.J. Roughley.
   "O-Linked Oligosaccharides of Human Articular Cartilage Proteogleyan"
   Biochem. Biophys. Acta 1982 716 277-282.
- Santer, V., A. Sriratana and D.A. Lowther.
   "Carrageenin-Induced Arthritis: V. A Morphological Study of the Development of Inflammation in Acute Arthritis"
   Seminars in Arthritis and Rheumatism. 1983 18 162-168.
- Fosang, A.J., C.J. Handley, V. Santer, D.A. Lowther, C.M.L. Harper and G.D. Thorburn.
   "Pregnancy-Related Changes in the Connective Tissue of the Ovine Cervix" Biol Reproduction 1984 30 1223-1235.
- Golds, E., V. Santer, J. Killackey and P.J. Roughley.
   "Mononuclear Cell Factors Stimulate the Concomitant Secretion of Distinct Latent Proteoglycan, Gelatin and Collagen Degrading Enzymes from Human Skin Fibroblasts and Synovial Cells"
   J. Rheumatol 1983 10 861-871.
- Santer, V.
  "Patents and Patenting A Primer for the Biotechnologist"
  Aust. J. Biotechnol 1988 <u>1</u> 25-30.
- Santer, V.
   "Problems in Obtaining Patent Protection in Biotechnology"
   Proceedings of the 8th Australian Biotechnology Conference, February 1989.
- Santer, V.
   "Problems in Obtaining Patent Protection for Biotechnology"
   Conference of the Institute of Patent Attorneys of Australia, March 1989.
- Santer, V.
   "Intellectual Property Protection for Plants Patents and Plant Variety Rights"
   Workshop on Intellectual Property Protection for Plants, July 1989.

- Santer, V.
   "Patents for Higher Animals and Plants"
   Proceedings of the 9th Australian Biotechnology Conference, September 1990.
- 32. Santer, V.
   "Patents for Higher Animals and Plants"
   Conference on Ethics and Intellectual Property, Melbourne, October 1990.
- 33. Santer, V."Patents in Biotechnology"Search 1993 24 77-81.
- Santer, V.
   Patents and the Human Genome Project: Implications of the Venter Application
   Proceedings of the 11th Australian Biotechnology Conference, September 1993
- Cox, G., S.S.H. Wong, V.B. Santer,
   "Patentability of Biotechnology Inventions in Countries of the Pacific Rim"
   Australasian Biotechnology, 1994 4 (5) 274-277
- Santer, V.
   "Does the Patent System Affect Research?"
   Proceedings of the Pacific Rim Biotechnology Conference, February 1995.
- Santer, V
   "Strategies for Maximising Patent Life'
   Second Australia/ Japan Symposium on Drug Design and Development, September 1996.
- Santer, V.
   "Intellectual Property Rights For Transgenic Crops"
   Workshop on Commercialisation of Transgenic Crops, March 1997
- 39. Santer, V.
   "Where the Wild Things Are: The Tension Between Patents and Traditional Knowledge"
   Proceedings of the 14<sup>th</sup> Australasian Biotechnology Conference, April 1998.
- Santer, V.
   "Developments in Australian Patent Law"
   Biotechnology Industry Organisation Conference, New York, June 1998.
- Santer, V.
   "Protecting Inventions in Combinatorial Chemistry"
   Third Australia-Japan Symposium on Drug Design and Development, Tokushima,
   September 1998.
- 42. Santer, V.

  "Recent changes in patent law: how do they impact on researchers and companies"

Conference on Advances in Diagnostic Technologies, Melbourne, May 1999

43. Santer, V.

"Recent changes in patent law: how do they impact on researchers and companies" Commercialising Health Innovations Forum, Melbourne, October 1999.

44. Santer, V.

"Intellectual Property and Patent Issues" in "Australian Biotechnology Report 1999" (Ernst & Young, 1999)

45. Santer, V.

"Patentability of genomics, bioinformatics and research tools"
Biotechnology Industry Organisation Conference, Boston, March 2000.

46. Santer, V.

"American Booty: Crossing the Threshold from Discovery to Patentable Invention" Fourth Australia/ Japan Symposium on Drug Design and Development, May 2000.

47. Santer, V.

"Bioprospecting, Traditional Rights and Patents" 15<sup>th</sup> Australasian Biotechnology Conference, July 2000.

48. Santer, V.

"Bioprospecting, Traditional Rights and Patents"
International Marine Biotechnology Conference, September 2000.

49. Santer, V.

"Patents for Research Tools: Problem or Promise?"

15<sup>th</sup> Australasian Biotechnology Conference, July 2001.

50. Santer, V.

"Cost-Effective Foreign Patenting"
Fifth Australia/ Japan Symposium on Drug Design and Development, May 2002.

51. Santer, V.

"Are genomics patents worthwhile?" AusBiotech conference, August 2002

# SUBMISSIONS ON BEHALF OF THE AUSTRALIAN BIOTECHNOLOGY ASSOCIATION

- Senate Select Committee on Agricultural and Veterinary Chemicals in Australia, 1989.
- Plant Variety Rights Office: re proposed revisions to the UPOV Convention, 21 July 1989.

- 3. Department of Foreign Affairs and Trade: re TRIPS Negotiations, 1990.
- 4. Expert Study of Legal Protection of Plants in Australia under Patent and Plant Variety Rights Legislation on behalf of the Patent Office and Plant Variety Rights Office, 24 August 1990.
- 5. House of Representatives Standing Committee on Industry, Science and Technology Inquiry into Genetically Modified Organisms (co-author), 16 November 1990.
- U.S. Association of Biotechnology Companies Patent Law Working Group re US
   Patent Law Reform and re Durden Case submitted to U.S. Advisory Commission
   on Patent Law Reform, 12 July 1991.
- 7. Proposed amendments to the Environment Protection Act and the Gene Technology Bill (April 2000).
- 8. Access to Australia's biological resources in Commonwealth areas (April 2000).
- 9. Intellectual Property and Competition Review Committee interim report (May 2000).